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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,767	04/15/2004	Gordon S. Sacks	WARF:004US	6706

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EXAMINER	
BLAND, LAYLA D	
ART UNIT	**PAPER NUMBER**
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,767	SACKS ET AL.	
	Examiner	Art Unit	
	Layla Bland	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/23/2004, 1/24/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This application is a continuation of U.S. Provisional Application 60/463,561, filed April 17, 2003. Claims 1-25 are pending and are examined on the merits herein.

Specification

The disclosure is objected to because of the following informalities: "suck" is misspelled as "such" on page 7, first line.

Appropriate correction is required.

Claim Objections

Claims 4 and 15 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 is drawn to L-glutamine and a solid or semi-solid medium. Claims 4 and 15 are drawn to claim 1 wherein the medium is water, which implies liquid water. If claims 4 and 15 were amended to include "frozen water" they would be in proper form.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 7-10, 12-17, 19-22, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Shinal, et al. (WO/2000/069470, November 23, 2000).

Claim 1 is drawn to a formulation comprising L-glutamine and a solid or semi-solid edible medium that dissolves on oral contact, claim 3 stipulates the formulation of claim 1 further comprises a flavor agent, an antiseptic or anesthetic, and claim 4 is drawn to the formulation of claim 1 wherein the medium is water. Claim 7 is drawn to the formulation of claim 1 provided as a lozenge, a dissolvable strip, a lollipop or a popsicle. Claims 8-10 are drawn to the formulation of claim 1, wherein the medium dissolves in response to an aqueous environment; or wherein the medium dissolves at or near normal body temperature; or wherein the medium dissolves in response to an aqueous environment and temperature at or near normal body temperatures. Claim 12 is drawn to the formulation of claim 1, wherein the formulation of claim 1 is solid at a temperature below about 0°C. Claims 13-17, 19 and 20 are drawn to the use of formulations mentioned above for the treatment of oral inflammation. Claims 21 and 22 are drawn to a stable drug formulation comprising L-glutamine frozen in a flavored

medium; wherein the L-glutamine is stable for about 3 to about 12 months. Claims 24 and 25 are drawn to a kit comprising L-glutamine and a flavor agent; and further comprising one or more of an edible medium, an anesthetic, a handle, and/or a mold.

Shinal, et al. teach a preparation of carbohydrate, glutamine and flavorings delivered via a lozenge, hard candy, ice cream formulation or a popsicle [page 25, lines 7-14], which is water in solid form (frozen). Shinal, et al. teach the glutamine preparation in the form of a lozenge, which is placed into the mouth and remains there while the surrounding fluids dissolve it [page 32, lines 1 and 2]. The mouth is by nature an aqueous environment at or near normal body temperature. Shinal, et al. also teach compositions for the treatment of oral lesions following radiation or chemotherapy [page 4, lines 5-12]. Shinal, et al. also teach that the glutamine of the described formulations has a stable shelf-life and can be provided to the patient well in advance of the time of administration [page 32, lines 10-13]. Furthermore, the stability of glutamine is an intrinsic property. Glutamine is known to be stable when frozen and there is nothing in the specification of the instant application to suggest why the glutamine used in these compositions would be any more or less stable than glutamine alone or in any other composition.

Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Sherratt, et al. (US 6,479,068 B1, November 12, 2002).

Claim 1 is drawn to a formulation comprising L-glutamine and a solid or semi-solid edible medium that dissolves on oral contact. Claim 2 is drawn to the formulation of claim 1, provided in a unit dose of about 20 to about 40 grams L-glutamine. Claims 5

and 6 are drawn to the formulation of claim 1, wherein the medium is a gel or pudding, or wherein the medium is a mixture of water and a gel or pudding.

Sherratt, et al. teach an oral glutamine composition in pudding [column 9, lines 14-17]. Pudding is a semi-solid edible medium and contains water, so the medium would be a mixture of water and pudding. Sherratt, et al. also teach an effective daily dose of glutamine to be about 30 grams [column 4, lines 54-57].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinal, et al. (WO/2000/069470, November 23, 2000) in view of Sherratt, et al. (US 6,479,068 B1, November 12, 2002).

Claim 11 is drawn to the formulation of claim 1, wherein the composition is provided as a popsicle comprising pudding, water, and a flavor agent. Claim 18 is drawn to the method of treating oral inflammation of claim 13, wherein the formulation is provided as a popsicle comprising pudding, water, and a flavor agent. Claim 23 is drawn to the frozen formulation of claim 21, provided in a unit dose of about 20 to 40 grams L-glutamine.

Shinal, et al. teach a glutamine composition in the form of ice cream or frozen confections such as the common popsicle [page 13, lines 13-14]. Shinal, et al. also teach glutamine compositions for the treatment of oral lesions following radiation or chemotherapy [page 4, lines 5-12] and teaches that frozen formulations can be especially effective for the treatment of oral and esophageal ulcers, since they can combine the beneficial effects of glutamine with the soothing effects of the cold mixture [page 13, lines 12-17].

Shinal, et al. does not teach a glutamine composition in the form of pudding and does not teach a dosage of about 20 grams to about 40 grams.

Sherratt, et al. teach an oral composition comprising L-glutamine [abstract] that can be mixed into moist food such as pudding [column 9, lines 16-17], which contains water and flavoring. Sherratt, et al. also teach an effective daily dose of glutamine to be about 30 grams [column 4, lines 54-57].

Sherratt, et al. does not teach a frozen composition.

One of ordinary skill in the art would be motivated to combine the frozen medium of Shinal, et al. with the dosage of Sherratt, et al. for the treatment of oral inflammation caused by chemotherapy or radiation in order to get the added benefit of the cold formulation with the appropriate dosage. One of ordinary skill in the art would be motivated to combine the popsicle of Shinal, et al. with the pudding of Sherratt, et al. in order to gain the added benefit of the cold composition with the taste of pudding, which some patients might prefer.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (703) 272-9572. The examiner can normally be reached on M-F 7:30AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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